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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,630	01/02/2001	Syed F.A. Hossainy	M-8618 US	1934

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EXAMINER	
MICHENER, JENNIFER KOLB	
ART UNIT	PAPER NUMBER
1762	11

DATE MAILED: 09/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

MK-11

Office Action Summary	Application No.	Applicant(s)	
	09/753,630	HOSSAINY ET AL.	
	Examiner	Art Unit	
	Jennifer Kolb Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37 and 40-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37 and 40-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

Based on Applicant's amended claims, the following new 112, 1st rejections are made:

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 37, 49, 53, 58, and those depending therefrom are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The word "aromatic" regarding the quaternary ammonium ion appears to be new matter. The Examiner cannot find a reference to this aromatic limitation within the originally-filed specification or claims. As one example among many, Examiner did find a teaching on page 4 of the specification that one exemplary heparin derivative may contain benzylalkonium groups. Examiner notes that benzyl groups are aromatic. However, disclosure of the species "benzylalkonium group" does not provide a basis for broadly claiming the entire "aromatic quaternary ammonium" genus.

Therefore the above claims are additionally rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "benzylalkonium", does not reasonably provide enablement for "aromatic quaternary ammonium". The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Claims 37 and 40-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
The additional "therapeutic substance" of step (c) appears to be new matter. The only therapeutic substance of the specification is the heparin derivative, which is claimed in step (b) of the claim. The Examiner cannot find a reference to this additional therapeutic substance within the originally-filed specification or claims.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. As necessitated by the cancellation of claim 38, the rejection of claim 38 is withdrawn. However, the subject matter of claim 38 has been incorporated into the text of claim 37. The limitation of claim 38, now in claim 37, is no longer vague and indefinite because it is now clear that Applicant intended, in amendment A, for the therapeutic substance to be in addition to the therapeutic heparin. However, now clear, this presents a new matter situation, as addressed above.

6. In light of Applicant's amendments, the rejection of claim 44 is withdrawn.

7. Examiner maintains the rejection of claim 48 for the incorporation of the trademark "DURAFLO". Examiner has carefully reviewed Applicant's arguments, including the MPEP citations. The MPEP requires either the meaning of DURAFLO to be accompanied by a sufficiently precise and definite definition or the meaning of DURAFLO to be defined in the literature. Applicant argues that both of these conditions are met by the definition of "commercial heparin derivative" from Baxter. However, Applicant goes on to state that no exact chemical name or formula for DURAFLO is known because it is kept secret by Baxter. Therefore, it does not appear that a "precise and definite" definition can be provided. In her search of US Patents containing the word DURAFLO, Examiner can find no definition there either. Therefore, it is Examiner's position that the MPEP conditions have not been met. Because there is no definition other than "a commercial heparin derivative", Examiner must maintain that the claim is indefinite because it does not indicate whether the same material made under a different name is equally operational and, therefore, an obvious variation for examination purposes. For examination purposes, Examiner asserts that the claim is met by a "commercial heparin derivative".

Based on Applicant's amendments, the following new 112, 2nd rejections are made:

8. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 requires the use of DURAFLO as the heparin complex of claim 37. Claim 37 requires the heparin complex to be one with an aromatic quaternary ammonium ion. In light of the fact that the formula and definition of DURAFLO are unknown, it is not clear how Applicant can know that DURAFLO contains an aromatic quaternary ammonium ion, as independent claim 37 requires of claim 48.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. The rejection of claims 37-38 as anticipated by Rowland has been withdrawn based on Applicant's amendment.

11. The rejection of claims 37 and 49-51 as being anticipated by Shah has been withdrawn based on Applicant's amendment.

12. The rejection of claims 37, 41, 48-51, and 58-59 as being anticipated by Ding has been withdrawn base don Applicant's amendment.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The rejection of claims 37-38, 41, 44, 48-51, and 58-59 as being unpatentable over Zhong in view of Shah has been withdrawn based on Applicant's amendment.

15. The rejection of claims 40, 43, and 52-57 as being unpatentable over Zhong in view of Shah and further in view of Hostettler has been withdrawn based on Applicant's amendment.

16. The rejection of claims 37-38, 40-43, 45-53, and 57 as being unpatentable over Hostettler in view of Shah has been withdrawn based on Applicant's amendment.

Based on Applicant's amendments, the following new 103 rejections are made:

17. Claims 37, 40-44, 48-55, 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,451,373 B1) in view of Ding et al. (US 6,316,018).

Hossainy teaches coating a stent with a therapeutic agent or combinations of therapeutic agents either separate from or together with a polymer (abstract; col. 4, line 8; col. 4, line 39; col. 6; Examples 3 and 4). Examples 3 and 4 teach that this polymer used with the therapeutic agent(s) may be ethylene vinyl alcohol (EVOH) copolymer. The therapeutic agent may be heparin (col. 4, lines 53-54; col. 6, line 5). When more than 1 therapeutic agents are chosen, a second therapeutic agent would be taught, as required by the claim. Because a solution is made of these chemicals, it is Examiner's position that the heparin, EVOH copolymer, and second therapeutic agent are dispersed with one another.

The broad teachings of heparin would be inclusive of the specific type of heparin required by Applicant and cites Ding et al. for teaching the use of heparin complexes with polymers on stent surfaces (col. 8; Example 1, line 42). The complex attached to the heparin of Ding may be benzalkonium chloride, an aromatic quaternary ammonium ion, as required by Applicant (col. 8, lines 28-32).

Since Hossainy teaches coating stents with EVOH and therapeutic agents, such as heparin, and Ding teaches coating stents with polymer and specific heparin complexes, such as those complexed with benzalkonium chloride, Ding would have reasonably suggested the use of his aromatic quaternary ammonium-heparin complex as the heparin used in Hossainy. It would have been obvious to one of ordinary skill in the art to use the teachings of Ding's types of heparins in the method of Hossainy with the expectation of similar, successful results of obtaining a non-thrombogenic/platelet-inhibiting stent.

The heparin compound of Ding appears to meet the definition of DURAFLO required in claim 48.

Regarding claims 40, 52, and 53 Hossainy teaches roughening prior to applying his EVOH-heparin coating (abstract).

Regarding claims 41-42, 57 Hossainy teaches application of a primer to his stent (abstract). This primer may be EVOH as well (col. 10, line 53).

Prior to application of any layers, Hossainy teaches creating depots in the surface of the stent (col. 7, line 31), which would roughen the surface prior to primer application, as required by claim 43.

Example 3 teaches heat-treating the coating at 60 degrees C, as is required by claims 44, 54, 55, 58, and 59.

Hossainy teaches the use of a combination of polymers for use with the heparin (col. 6, line 65) and provides examples of polymers other than EVOH, above, such as polycaprolactone, among others (col. 5, lines 60-65). These polymers would act as the adhesion enhancer required by claims 49 and 50.

Hossainy teaches dip-coating, as required by claim 51.

18. Claims 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,451,373 B1) in view of Ding et al. (US 6,316,018), as applied to claims 37, 40-44, 48-55, 57-59 above, and further in view of Shah.

Hossainy and Ding teach that which is disclosed above, particularly the use of a primer coating prior to coating a stent with heparin complexes. What these references fail to teach is the use of a chlorosilane primer.

Shah teaches a number of silane primers useful in linking heparin to stent substrates, such as trialkoxysilanes and chlorosilanes (col. 5, lines 34-42).

Since Hossainy and Ding teach the use of a primer to attach heparin complexes to stents and Shah teaches the use of chlorosilanes as a primer, Shah would have reasonably suggested the use of chlorosilanes as a coupling agent in Hossainy and Ding. It would have been obvious to one of ordinary skill in the art to use the primer of

Shah in the method of Hossainy and Ding with the expectation of similar, successful heparin attachment to stents.

19. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,451,373 B1) in view of Ding et al. (US 6,316,018), as applied to claims 37, 40-44, 48-55, 57-59 above, and further in view of Haji et al. (US 5,909,633). Hossainy and Ding teach that which is disclosed above regarding roughening a substrate prior to coating, but these references fail to specifically teach roughening by argon plasma etching.

Haji et al. is cited to teach the use of argon plasma etching to roughen a metal substrate (col. 4, lines 10-30).

Since Ding and Hossainy teach a variety of methods of roughening a substrate and Haji provides a means of doing so using plasma etching, Haji would have reasonably suggested the use of argon plasma etching in the method of Hossainy and Ding with the reasonable expectation of successful roughening prior to applying a coating composition.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Iguchi teaches coating stents with a combination of ethylene vinyl alcohol copolymer and an antiplatelet agent. While not ideal, Iguchi teaches that

heparin is a commonly used antiplatelet agent. Onishi teaches coating stents with heparin in an ethylene vinyl alcohol copolymer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer Kolb Michener
September 23, 2002

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